K062157
p. 1 of 3

OCT 13 2006

510 (K) SUMMARY

As Required by the Safe Medical Devices Act of 1990

Apex Dental Materials, Inc.
23329 Mallard Court
Deer Park, IL 60010
Phone: (877) 273-9123

510 (K) Submission Date: July21st, 2006

Contact Person: Chris Kulton

Device Name:
Trade Name: CONFORM™
Common Name: Material, Tooth Shade, Resin
Classification Name: Tooth Shade Resin Material, per 21 CFR parts 872.3690

Classification:
Regulatory Class: 2
Product Code: EBF

IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICE

PREDICATE DEVICE

AELITEFLO® (Bisco, Inc. K955292) is a flowable composite material designed to act as a cavity filling or lining material. This system is applied directly to bonded tooth surfaces to effectively replace removed tooth structure.

AELITEFLO® (Bisco, Inc. K955292) is a methacrylate based composite material filled with various inorganic glasses to provide strength, wear and radiopacity characteristics.

AELITEFLO® is a single paste material that is used directly with dental bonding systems. It

hardens by a photo initiated polymerization mechanism employing a light initiator, and a chemical activator.

Summary continued:

DESCRIPTION OF APPLICATION DEVICE

CONFORM™ is a light activate (photo initiated, free radical polymerization), flowable hybrid composite material designed to act as a filling material in small restorations or as a liner material for larger restorations. CONFORM™ has been designed to provide a flowable material with a high level of thixotropic behavior. The material also contains fillers to optimize the cured strength and radiopacity properties.

CONFORM™ is a methacrylate (BisGMA) based material that has been designed to work effectively with methacrylate based adhesives and composites currently sold into the dental market.

INTENDED USES OF APPLICANT DEVICE

CONFORM™ is a light-cured composite with flow characteristics that make it ideal for Class V restorations, as well as Class III, and small Class IV restorations. Other uses of this material are as a liner for Class I and II restorations, pit and fissure sealants, the repair of marginal defects, small core build-ups, porcelain repair, porcelain veneer cementation or as a flowable composite for bonding splints into place.

- Class V
- Class III
- Cavity Liner

- Pit and Fissure sealant
- Porcelain repair
- Margin repair
- Core build ups
- Buccal repair

Summary continued:

PERFORMANCE CHARACTERISTICS and CONCEPTS

CONFORM™ has similar handling to the AELITEFLO® (510K number K955292, Bisco, Inc.) composite. From the physical testing observations and analysis, including diametric tensile strength and compressive strength, we suggest that CONFORM™™ is substantially equivalent to AELITEFLO® (510K number K955292, Bisco, Inc.). Along with this we would suggest the individual components of CONFORM™ are long time industry standards and are utilized in numerous dental composite products currently marketed in the United States (see Confidential Formulation Details on page 5).

Equivalent Product and Manufacturer	Corresponding 510(k) Numbers
AELITEFLO® (Bisco, Inc.)	K955292
PERMAFLO® (Ultradent Products Inc.)	K974413

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2006

Mr. Chris Kulton
Apex Dental Materials, Incorporated
23329 Mallard Court
Dear Park, Illinois 60010

Re: K062157
Trade/Device Name: Conform™
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: July 21, 2006
Received: July 31, 2006

Dear Mr. Kulton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K062157

Device name: CONFORM™

Indications For Use:

CONFORM™ is a light cured (free radical polymerization), flowable composite material, designed for use as a filling material for small restorations, a sealant material for occlusal surfaces, or a lining material in the base of large restorations.

CONFORM™ is a versatile composite material which, when utilized properly, provides a strong, wear resistant material for dental restorations. CONFORM™ can also be used as the initial filled layer or liner of a cavity restoration. When used as a liner, the material provides a strong base that assures the mechanical interface between the bonded tooth substrate and a highly filled composite are optimal. CONFORM™ is compatible with all other methacrylate based dental materials.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRL, Office of Device Evaluation (ODE)

Kevin Mulloy for M.S.R

(Division Sign-Off)

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K062157

Prescription use X
(Per 21 CFR 801.109

OR

Over-The- Counter Use

(Optional Format 1-2-96)